

# Exhibit A

IN THE DISTRICT OF THE UNITED STATES OF AMERICA  
FOR THE SOUTHERN DISTRICT OF ILLINOIS

D.W.K., Jr. and parents Mary &  
Daniel Kaleta,

Plaintiff(s), ) Case No. 14-847-NJR-SCW

vs.

ABBOTT LABORATORIES, INC.,

Defendant(s).

TRIAL DAY 1  
(a.m. session)

BE IT REMEMBERED AND CERTIFIED that heretofore on 03/02/2015,  
the same being one of the regular judicial days in and for the  
United States District Court for the Southern District of  
Illinois, **Honorable Nancy J. Rosenstengel**, United States  
District Judge, presiding, the following proceedings were  
recorded by mechanical stenography; transcript produced by  
computer.

**REPORTED BY:** Molly N. Clayton, RPR, FCRR, Official  
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APPEARANCES:

**John Eddie Williams and John T. Boundas** of Williams  
Kherkher Hart Boundas LLP, 8441 Gulf Freeway, Suite 600,  
Houston, TX 77017; and,

**Phillip Sampson** of Bracewell & Giuliani LLP, 711  
Louisiana, Suite 2300, Houston, TX 77002; and,

**Kenneth T. Fibich** of Fibich Hampton Leebron Briggs &  
Josephson, LLP, 1150 Bissonnet, Houston, TX 77005; and,

**FOR DEFENDANT: Dan H. Ball** of Bryan Cave - St. Louis, 211  
North Broadway, One Metropolitan Square, Suite 3600, St. Louis,  
MO 63102; and,

**Paul F. Strain and B. Michael MacWilliams** of Venable LLP,  
750 East Pratt St, Suite 900, Baltimore, MD 21202

Day 1-a.m., Pg. 3

INDEX OF WITNESS EXAMINATION

DX CX R-DX R-CX

No witness testimony.

INDEX OF EXHIBITS

EXHIBIT DESCRIPTION Id'D Rev'd

No exhibits identified or received.

MISCELLANEOUS

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Day 1-a.m., Pg. 4

(Court convened)

(Following proceedings held outside presence of Venire 1-29:)

**THE CLERK:** D.W.K., Jr., et al., versus Abbott  
Laboratories, Inc., Case Number 14-cv-847, is called for the  
first day of civil jury trial.

Will the parties identify themselves for the record?

**MR. FIBICH:** Good morning, your Honor, Tommy Fibich,  
on behalf of the plaintiffs.

**THE COURT:** Good morning, Mr. Fibich.

**MR. WILLIAMS:** Good morning. John Eddie Williams,  
plaintiffs.

**THE COURT:** Mr. Williams.

**MR. BOUNDAS:** John Boundas, for the plaintiffs.

**THE COURT:** Good morning, Mr. Boundas.

**MR. SAMPSON:** Phillip Sampson, plaintiffs, your Honor.

**THE COURT:** Good morning.

**MR. BALL:** Dan Ball, for Abbott.

**THE COURT:** Good morning, Mr. Ball.

**MR. MacWILLIAMS:** Good morning, your Honor. Michael  
MacWilliams for Abbott.

**THE COURT:** Good morning, Mr. MacWilliams.

**MR. STRAIN:** Good morning, your Honor, Paul Strain,  
for the defense.

**THE COURT:** Good morning, Mr. Strain.

Well, good morning, everyone, and welcome. I hope

1 medicines. most of them are completely useless for the kid #1803  
2 of epilepsy Mrs. Kaleta has, unfortunately.

3 In fact, there's a doctor who's going to come in  
4 here to testify for the plaintiffs, and he's going to admit  
5 that there are only two others that have even a theoretical  
6 possibility of helping Mrs. Kaleta back at the time she was  
7 pregnant with D■■■■, only two others. They're called  
8 Lamictal and Topamax. And you might have to double them up,  
9 which, of course, is bad to take two rather than one.

10 But just to show you what the doctors would have to  
11 choose from, those two drugs, the FDA categorized as a C.  
12 So if a doctor felt, *Should I try Lamictal? Should I try*  
13 *Depakote?* and wanted to know which one has more risk, the  
14 FDA's telling them which one has more risk.

15 You look at the Depakote warning label. You look  
16 at the Lamictal warning label, and then you know. You know  
17 what the relative risk is. There's no, there's just no  
18 mystery about it. So -- and that was in the warning label  
19 from the time Depakote began, so way back. All the doctors,  
20 whoever prescribed it, dealt with Mrs. Kaleta with Depakote,  
21 knew all this.

22 For example, you heard the name Dr. Taber.  
23 Dr. Taber -- you heard it this morning and I mentioned it  
24 again a moment ago. Dr. Taber testified that he knew  
25 Depakote had a spina bifida risk that was not present in

1 other medications. He knew that. He knew it because the  
2 warning label was effective. He also testified that he was  
3 well aware and told Mrs. Kaleta the risk occurs in the first  
4 couple of weeks of pregnancy, that Depakote had special  
5 birth defect risks that other drugs didn't have.

6 And he knew all about what spina bifida is and  
7 described it in -- when he was warning Mrs. Kaleta,  
8 described to her spina bifida in very graphic terms I'm not  
9 even going to repeat here; in very graphic terms just how  
10 bad spina bifida could be. So he knew it and he told her,  
11 and he'll testify to that when we submit his testimony.

12 And Dr. McGonagle, her neurologist in 1999, has  
13 testified that he also knew Depakote had special risks and  
14 greater birth defect risks than other epilepsy medicine.  
15 There's no mistake about this. These doctors knew. And one  
16 of the reasons they knew is -- obviously, Dr. McGonagle said  
17 he knew it from the get-go, in fact, when he got out of  
18 medical school. But one of the reasons he knew was because  
19 of the warning label and how Abbott took the responsibility  
20 seriously.

21 Now, one of the things that happened -- and maybe  
22 the most important thing -- between when Dr. Taber  
23 prescribed Depakote for Mrs. Kaleta and when Dr. McGonagle  
24 prescribed Depakote for Mrs. Kaleta, one of the things that  
25 happened was the FDA made an important decision about

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1 Depakote, and that decision was to require Abbott to have a  
2 black box warning label for birth defects, black box -- FDA  
3 black box birth defect warning. The black box warning comes  
4 right out of FDA regulations. It is the strongest warning  
5 that FDA regulations allow, the strongest warning that FDA  
6 regulations allow.

7 There are, in FDA-approved warning labels -- and  
8 you all know that pharmaceutical companies aren't free  
9 agents with their warning labels. The FDA is right involved  
10 and has to approve the warnings and all the rest. The  
11 FDA-approved warning labels have different categories and  
12 levels of warnings, and one of them -- it's a section right  
13 in the warning labels. One of them is called "Precautions",  
14 and a whole lot of drugs have precautions for the doctors  
15 about that drug.

16 And the next level up, the higher level up is  
17 warnings themselves. They're called warnings themselves.  
18 And many drugs have warnings as well; have precautions and  
19 warnings. Above that, sitting above that is the strongest  
20 warning that the FDA requires to be right up front. Right  
21 at the start of the warning label is the FDA black box  
22 warning.

23 Now, that black box warning is not only the FDA's  
24 strongest allowed warning category. That FDA black box  
25 warning is owned by the FDA. Abbott put that black box

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1 warning when the FDA said to in 1996 in its physician's  
2 warning label.

3 That's tiny, but I want you to see the language.

4 If I may put that up, Your Honor?

5 *THE COURT:* You may.

6 *MR. STRAIN:* I understand it won't block your view.

7 *THE COURT:* No. That's fine.

8 *MR. STRAIN:* What we're looking at is the FDA's  
9 black box warning for birth defects. The first word is  
10 "teratogenicity." I had to learn how to pronounce that,  
11 "teratogenicity." It's a doctor's word for birth defects.  
12 To a doctor, that means birth defects.

13 And you see how it says -- you see how it says,  
14 teratogenic effects -- that means birth defects -- such as;  
15 not only, but such as neural tube defects. That's a general  
16 term for spina bifida. And then so there's no mistake,  
17 spina bifida itself. That's what the FDA said to put in the  
18 black box warning for Depakote.

19 And I said the FDA owns the black box warning.  
20 That's what I mean. Because what the FDA does when it's the  
21 black box warning is, the FDA says, *This is the language.*  
22 *You have to do it. You have to do that and only that.*  
23 *Don't play with those words. Don't change them. That's it.*  
24 *Carve it in stone. That's what it has to be.*

25 The FDA owns the black box warning. And what I've

1 medicine?

2 **A.** Pediatrics, which is the first one; pubic health or  
3 preventive medicine; and third, genetics.

4 **Q.** Now, you have been a pubic health officer?

5 **A.** Yes, sir.

6 **Q.** And you served in a branch of the military, I guess. What  
7 rank did you achieve?

8 **A.** Well, we call it -- it is the pubic health service, and we  
9 call it a uniform service. It is not a gun-toting military,  
10 okay. But it is Public Health Service. It grew up providing  
11 medical care to merchant seaman, is where it grew up, and,  
12 therefore, the uniforms look like Navy uniforms. But, yes, I'm  
13 a retired captain in the United States Public Health Service.

14 **Q.** Did you have to wear a uniform when you went to work every  
15 day?

16 **A.** Not every day. But once Dr. Koop became the Surgeon  
17 General, he thought that we ought to wear uniforms, and so the  
18 order came down that we should wear uniforms. And on every  
19 Wednesday at CDC, that was the standard, we wore uniforms. You  
20 could wear them any day, but I usually wore mine just on  
21 Wednesdays.

22 **Q.** Okay. How many years did you serve in the Pubic Health  
23 Service?

24 **A.** For 30 years.

25 **Q.** What made you to decide to serve in the Pubic Health

1 time.

2 Q. Okay. Now, in all of that, why didn't you finish college?

3 A. Well, he's referring to the fact that I only went to  
4 college for three years. And I -- at that time, there was  
5 some -- if you did well enough in college, you might be  
6 admitted to medical school, and I was fortunate enough not only  
7 to be admitted to medical school, but I got a full scholarship  
8 to go to medical school, which was really a lucky day for me  
9 and my family.

10 Q. You and I are southern boys, and our moms taught us to be  
11 modest, but I want to ask you about some things. Put modesty  
12 aside because I want this jury to appreciate what accolades you  
13 have received over the years. So I'm going to embarrass you a  
14 little bit. Did you start wining awards in medical school?

15 A. Um, well, I won a scholarship to get there. So that's for  
16 sure.

17 Q. And if I were to go through your CV, I've seen dozens of  
18 awards you have received over the years, correct?

19 A. Yes.

20 Q. And have you received lifetime achievement awards?

21 A. Yes. Spina Bifida Association. And I won the Watson prize  
22 at the CDC when I left, which was essentially a similar kind of  
23 award.

24 Q. You are being modest. The Watson prize is given to the  
25 highest -- it is for distinguished service for the CDC,

1 correct?

2 A. That is correct.

3 Q. It's the highest award they give?

4 A. That is correct.

5 Q. You have also been presented lifetime achievement awards by  
6 Spina Bifida Association, March of Dimes?

7 A. Yes.

8 Q. You are being modest.

9 A. Yes.

10 Q. Okay. Have you ever been named person of the week by ABC  
11 News, Peter Jennings?

12 A. Well, yes, I was. And it was an very, very interesting  
13 day. And so, yes, that's true I was. They made me sign my  
14 name, which is almost illegible, and it was shown on national  
15 television as I wrote my name out.

16 Q. What is the National Institute of Health?

17 A. The National Institute of Health is one part of the United  
18 States -- or the Department of Health, Education, and Welfare.  
19 And it is the unit that is in charge of funding biomedical  
20 research.

21 Q. Were you elected -- you have been elected by your peers  
22 into what group?

23 A. Do you mean the Institute of Medicine?

24 Q. Thank you for correcting.

25 What is the Institute of Medicine?

1     **A.** So the Institute of Medicine is a rather elite body of  
2     people interested in medicine that was formed to help the  
3     government make difficult decisions about many different  
4     things. And the advantage of the Institute of Medicine is  
5     that -- and its process is that it allows a very rigorous and  
6     unbiased review of evidence. And they put that together and  
7     try to interpret it so people use it in the Army or in the VA  
8     or others can make the proper decisions from that. It's been  
9     very visible, for example, at reviewing the data on the safety  
10    of vaccines that have been in the news a lot.

11    **Q.** Common on. How important is it that people receive an  
12    invitation by their peers to join the Institute of Medicine?

13    **A.** Well, it's clearly the biggest honor that I've ever had,  
14    was to be elected to the Institute of Medicine.

15    **Q.** And that's a very limited society, correct?

16    **A.** About 50, 60 people a year out of the whole country are  
17    elected. My mother was very proud.

18    **Q.** Okay. In addition to that, you have written extensively?

19    **A.** Yes, sir.

20    **Q.** You have been an author of many papers over the years.

21    **A.** That is correct.

22    **Q.** And you have been involved in some societies, and I want to  
23    ask you: The International Clearinghouse for Birth Defects,  
24    have you been involved with the International Clearinghouse for  
25    Birth Defects?

1     **A.** Yes, I have been. I was involved with it for many years,  
2     and people who worked for me at CDC after that continued to be  
3     involved in it. It was an organization, a rather small  
4     organization, but it was an organization of birth defects  
5     monitoring programs.

6             And we had one of those in Atlanta, and that's what I  
7     worked on when I first went there. And what we did was to go  
8     to every hospital in Atlanta, and if a baby -- or if a woman  
9     had a baby with a birth defect, we would count that baby, and  
10    we would find out information about where they lived.

11            And later some of the those babies would be -- some of  
12    those women would be interviewed, in trying to determine what  
13    exposures might they have had in pregnancy that might have  
14    explained the cause of this birth defect.

15     **Q.** By the way, the International Clearinghouse for Birth  
16    Defects, the relevance of that was in 1982. Is that the -- we  
17    have heard about Dr. Robert from Lyon. Was Dr. Robert a member  
18    of the international clearinghouse?

19     **A.** So the members are the programs, okay.

20     **Q.** Oh, okay.

21     **A.** But the programs are represented, and the people that come  
22    to the meeting were people like me. I represented the Atlanta  
23    birth defects surveillance system and Dr. Robert represented  
24    the Lyon system. Yes.

25     **Q.** Well, who was the head of International Clearinghouse for



1 Birth Defects back in 1982?

2 **A.** I was the president that year. So I was president -- and I  
3 was president another year, but that year I was president of  
4 that organization.

5 **Q.** We are going to come back to that in detail, if we can  
6 Doctor. But I'm going to move on.

7 Have you served on other societies? Like the Teratology  
8 Society, have you served them?

9 **A.** Yes. And to restate what is teratology and teratogens,  
10 teratology -- it is a terrible word. And we have tried to  
11 change the name of this organization, but we haven't gotten it  
12 changed yet. But "tera" comes from monster, which was  
13 animals -- baby animals with very bad birth defects is sort of  
14 where it comes from.

15 And so, yes, I was the president of that organization also.

16 **Q.** Thirty years in public health, you retired in what year?

17 **A.** 1998.

18 **Q.** And since then, what have you done?

19 **A.** Since then, my primary focus has been on trying to prevent  
20 spina bifida that's caused by there not being enough folic  
21 acid.

22 **Q.** I'm going to get to that. I don't want to interrupt you.  
23 By the way, this is your first time ever to testify, isn't it?

24 **A.** It is. I'm a bit of a rookie, so I hope I behave.

25 **Q.** I bet you do.

1           Okay. So, Dr. Oakley, are you a professor of medicine?

2       **A.** Well, I'm a professor of pediatrics, and I am a professor  
3       of epidemiology. That's where my main appointment is, a  
4       research professor of -- of epidemiology. My main point is in  
5       the school of public health.

6       **Q.** And at what university?

7       **A.** At Emory University, and the school is called the Rollins  
8       School of Public Health of Emory University.

9       **Q.** And you have received awards there?

10      **A.** Yes.

11      **Q.** And you have overseen -- you have mentored students as they  
12      get their master's degrees and advanced training in those  
13      areas.

14      **A.** That is correct.

15      **Q.** And if you would, you live in what city?

16      **A.** I live in Atlanta, Georgia.

17      **Q.** And your age, if I could?

18      **A.** Kind of personal, isn't it?

19           Okay. I'm 74. I'll be 75 in June.

20      **Q.** You told me 74 1/2.

21      **A.** Yes, sir, 74 1/2.

22      **Q.** Okay.

23      **A.** I'm proud of it, by the way.

24      **Q.** So if I may, I want to talk to you, you mentioned folic  
25      acid.

1     *missing arms, missing parts of their legs, this is a*  
2     *bigger deal than that.*

3             There is no cure for that, Your Honor.

4             THE COURT: Okay. Well, here's -- here is another  
5     thing that I think we could do and that is, I could  
6     individually poll the jurors to ask if they even know what  
7     Thalidomide is. Some people, of a certain age, don't even  
8     know what it is. And I could bring them in one at a time  
9     and ask them if they heard it, if they know what it is.  
10    If they know what it is, do they understand that it has  
11    nothing to do with this case and that, could they  
12    disregard that and decide the case on the evidence and not  
13    on any reference that has been made to that drug.

14            We have 12 jurors. So, if we have a juror who  
15    says, *Yes, I know what it is and I can't put it out of my*  
16    *mind*, we could let that juror go.

17            MR. STRAIN: I'm afraid, Your Honor, that that  
18    would further accentuate the prejudice because of the 12  
19    jurors, if one knows and then is released, the 11  
20    remaining will have heard it, with good intentions from  
21    Your Honor, and that would accentuate the problem. So, I  
22    would ask that we not do that, Your Honor.

23            MR. BOUNDAS: Your Honor, from the plaintiff's  
24    perspective, and I hope I'm not misspeaking the way it,  
25    the sequence of how it happened, was I think that Dr.

1 MR. BOUNDAS: Your Honor, if I can address that?

2 THE COURT: You can respond briefly.

3 MR. BOUNDAS: Thank you. I think Mr. Strain hit  
4 on the point there. They're arguing, Thalidomide, whether  
5 or not it is relevant, we can have a debate about it,  
6 okay? But I haven't heard anything that -- let's go back  
7 to the case law -- that they can no longer get a fair  
8 trial because this has so infected the jury's ability to  
9 address the evidence.

10 In other words, if these people now, because they  
11 heard Mr. -- Dr. Oakley inadvertently reference  
12 Thalidomide, even if irrelevant, is so prejudicial and so  
13 unfair that we cannot conduct the rest of this three-week  
14 trial because of what Dr. Oakley -- and I don't think  
15 there's any dispute -- inadvertently stated?

16 Here's what's happening: Abbott is making an  
17 assumption that somebody saying Thalidomide in the United  
18 States of America or, better yet, in the St. Louis area,  
19 pops something into someone's mind that makes it so, it  
20 clouds them so much that they can no longer weigh the  
21 evidence fairly, that I suggest, Your Honor, is an  
22 assumption. It -- I bet you, if we polled everyone -- you  
23 know, I was talking to Mr. Sampson. He didn't know what  
24 Thalidomide was before we got into this litigation.

25 THE COURT: well, that's why I asked, that's why I

1 asked about polling the jury because I, I polled my law  
2 clerks and they don't know what it is. So, a lot of  
3 people don't.

4 So, well, I'm going to take the motion under  
5 advisement.

6 Just to be clear, you do not want a curative  
7 instruction at this time?

8 MR. STRAIN: I do not, your Honor, for the reason  
9 I stated. Thank you.

10 THE COURT: And you do not want me to poll the  
11 jury at this time?

12 MR. STRAIN: I do not, for the reason I stated,  
13 Your Honor.

14 THE COURT: Okay. well, I'm going to take the  
15 motion under advisement.

16 Dr. Oakley, you understand, no reference to  
17 Thalidomide?

18 THE WITNESS: I understand.

19 THE COURT: Okay. And we'll proceed.

20 MR. STRAIN: As Your Honor has it under  
21 advisement, I know you will but, directing attention to,  
22 among other things, to page 34, with the reference to  
23 *missing arms and parts of legs due to Thalidomide --*  
24 *quoting from the rough -- this is a bigger deal than that.*

25 THE COURT: Okay.